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AMMSYS Research Inc.

A Clinical Research Organization

May 30, 2000

Dockets Management Branch
HFA-305
Docket No. 00N-1256-FDA Regulation of OTC Drug Products Hearing
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1256 FDA Regulation of OTC Drug Products Hearing
Public Hearing Wednesday, June 28 and Thursday, June 29, 2000: Written
Notice of Participation

Dear Sir/Madam:

This letter is written notice of participation in the public hearings (Docket 00N-1256-21
CRF-Part-15) scheduled June 28 and 29, 2000.

I request 20 minutes for comments related to *Paragraph C: Consumer Understanding
FDA Notice Federal Register April 27, 2000 (Volume 65, Number 82, Pages 24704-
24706)*. My comments will follow the outline provided below.

I. Statement of Purpose – OTC Switch Decisions (4 minutes)

- No need for radical change in current process.
- Current process will work if FDA works with industry.
- Each switch should be considered individually – not by general guidelines.
- FDA should pose questions/concerns. Industry has the resources to validate hypotheses and answer FDA concerns.
- Data should drive individual switch decisions – not predetermined policy.
- Use studies – a tool for validating hypotheses and determining consumer understanding and reaction.

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II. Historic Overview OTC Switches (brief 3-4 minutes)

- Scope of switches
- Evolving research methodology
- Consumer understanding and health impact

III. Support Data & References: Case Study NRT Product– 3400 Subjects (12 minutes)

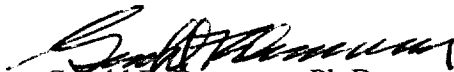
- Research questions/objectives
- Creative Methodology
- Study results
- Consumer understanding and health impact

I am providing personal and demographic information as requested:

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Telephone: (410) 266-1586
Affiliation: None
Sponsor: AMMSYS Research Inc. (Gerald F. Dunaway, President)

Thank you in advance for considering this written notice of participation.

Sincerely,


Gerald F. Dunaway, Ph.D.
President